United States Patent [19]

Norton et al.

[11] **3,878,839**

[45] **Apr. 22, 1975**

[54] **CARDIAC ASSIST APPARATUS**

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[73] Assignee: **Hemodyne, Inc.**, Norfolk, Mass.

[22] Filed: **Feb. 15, 1973**

[21] Appl. No.: **332,629**

[52] **U.S. Cl.** **128/64**

[51] **Int. Cl.** **A61h 7/00**

[58] **Field of Search** ..... 128/64, 24 R, 297, 299, 128/60, 39, 40

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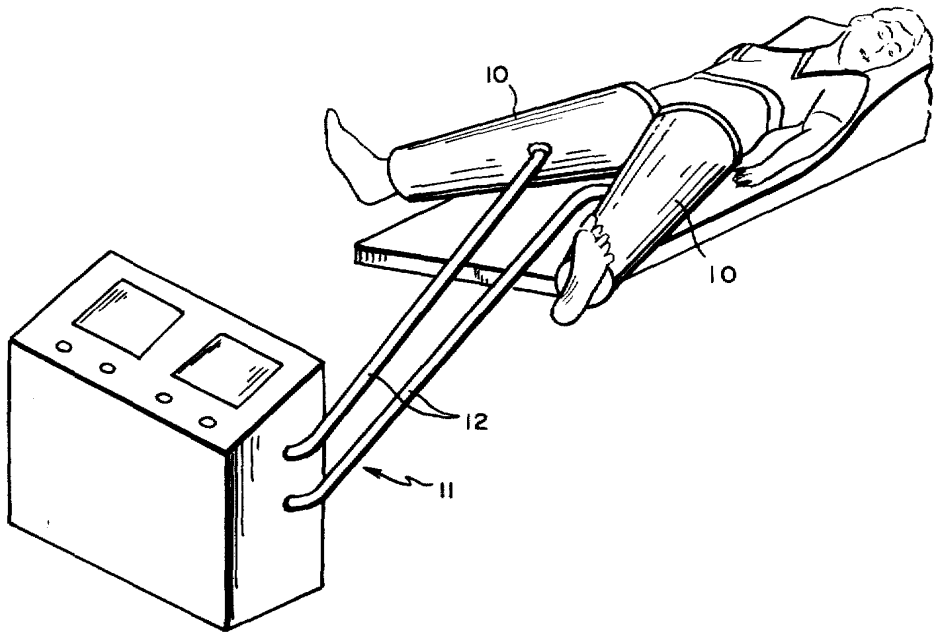
Primary Examiner—Lawrence W. Trapp
Attorney, Agent, or Firm—Dike, Bronstein, Roberts, Cushman & Pfund

[57] **ABSTRACT**

An apparatus for providing external assistance for the circulation of blood in a patient wherein a substantially rigid housing encloses a portion of the patient's body, such as the legs, and a closed pneumatic pressure actuation system is used to actuate a pressure medium, at least a portion of which is gaseous, within the housing to cyclically apply pressure to the body in synchronism with the patient's heartbeat. The housing may be fabricated to provide either a fixed volume or a variable volume therein. Means are provided for effecting an efficient transfer of energy from the actuation system to the pressure medium and thence to the patient's body.

29 Claims, 17 Drawing Figures



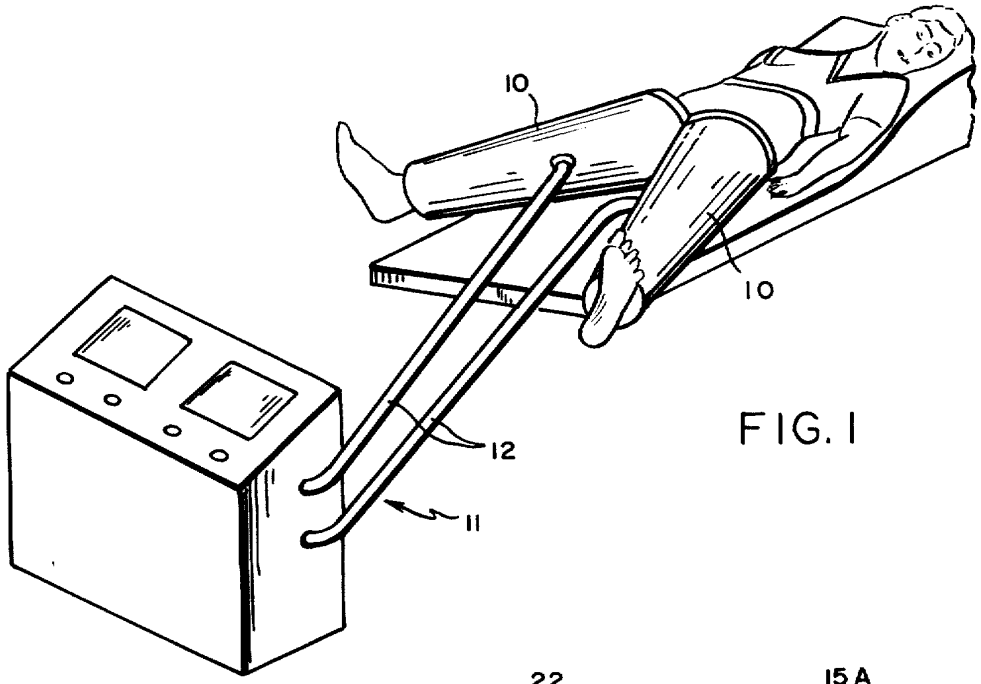


FIG. 1

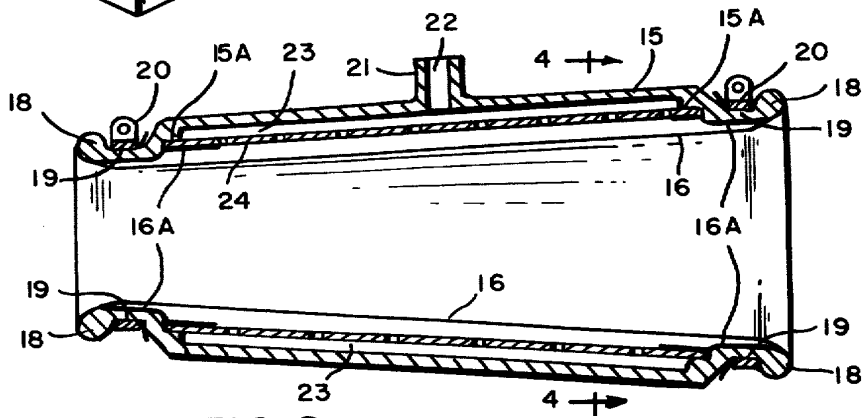


FIG. 2

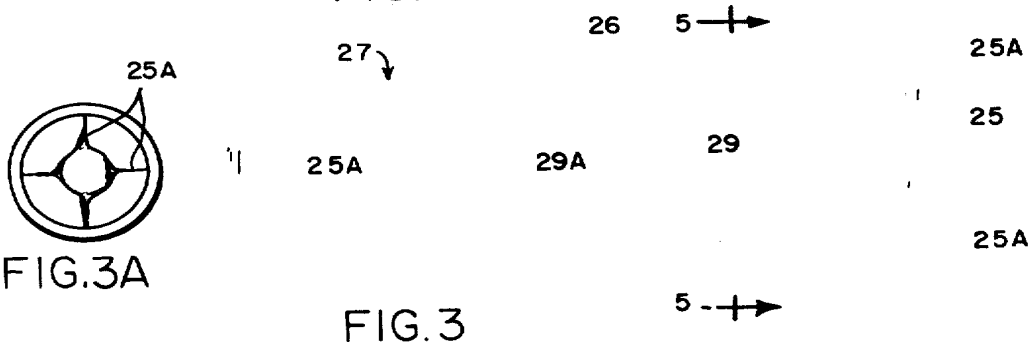


FIG. 3A

FIG. 3

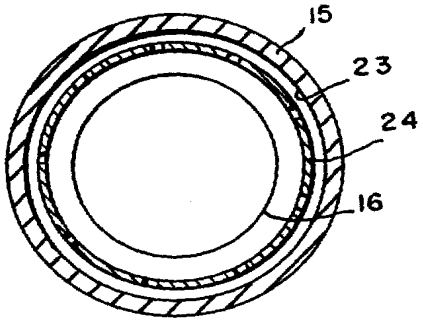


FIG. 4

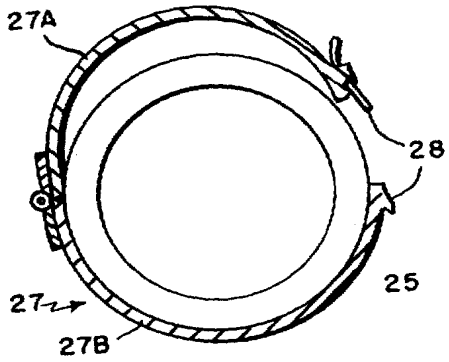


FIG 5

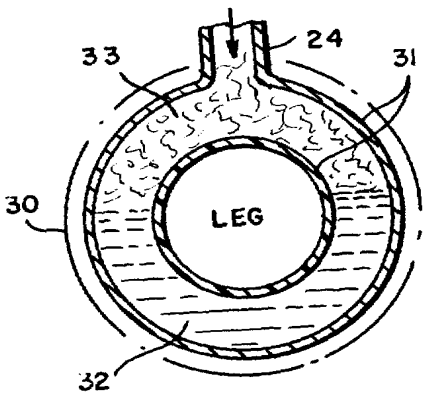


FIG.6

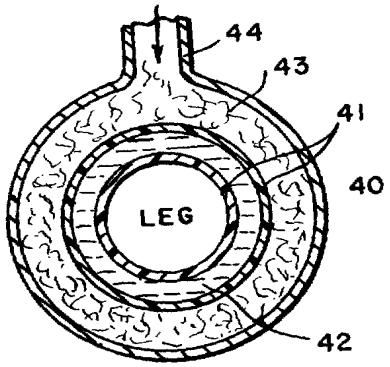


FIG. 7

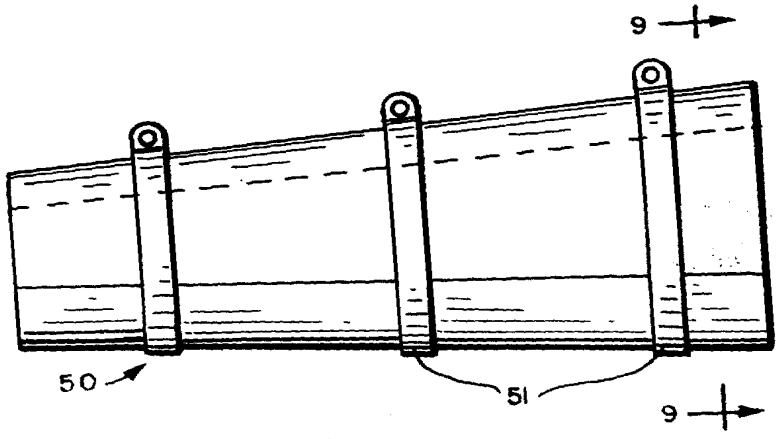


FIG.8

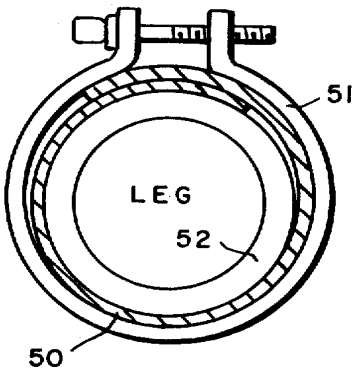


FIG.9

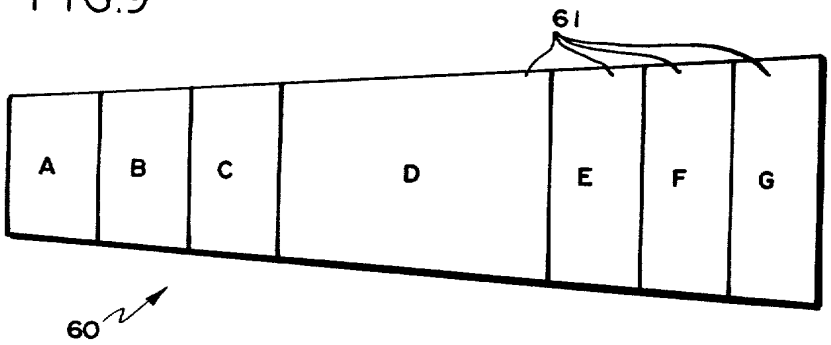


FIG.10

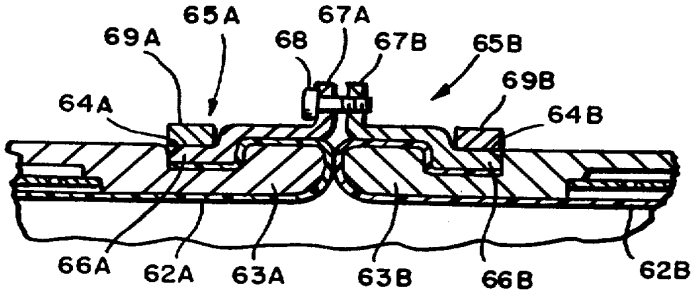


FIG.11

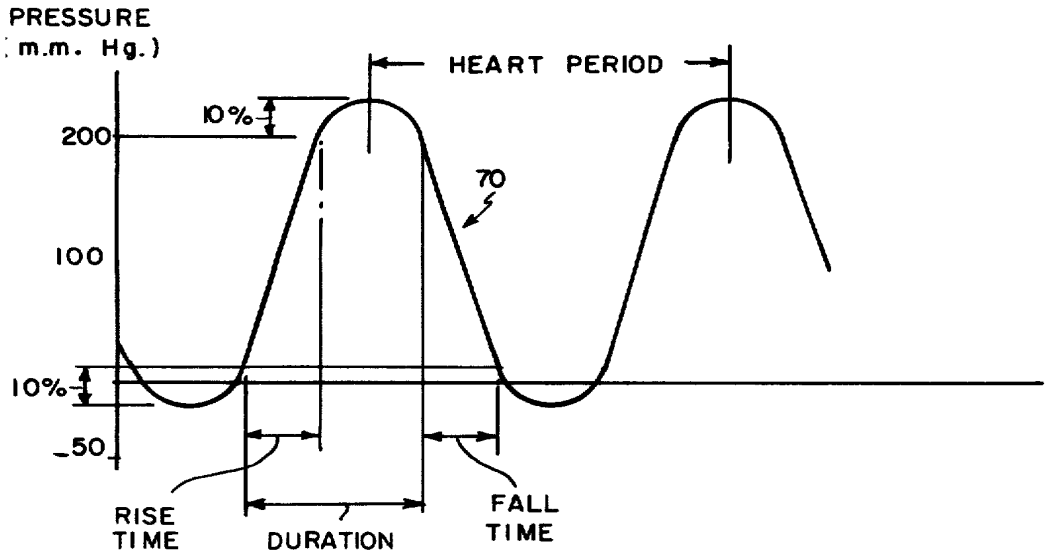

PRESSURE
(m.m. Hg.)
HEART PERIOD
10%
200
70
100
10%
-50
RISE
TIME
DURATION
FALL
TIME

FIG. 12

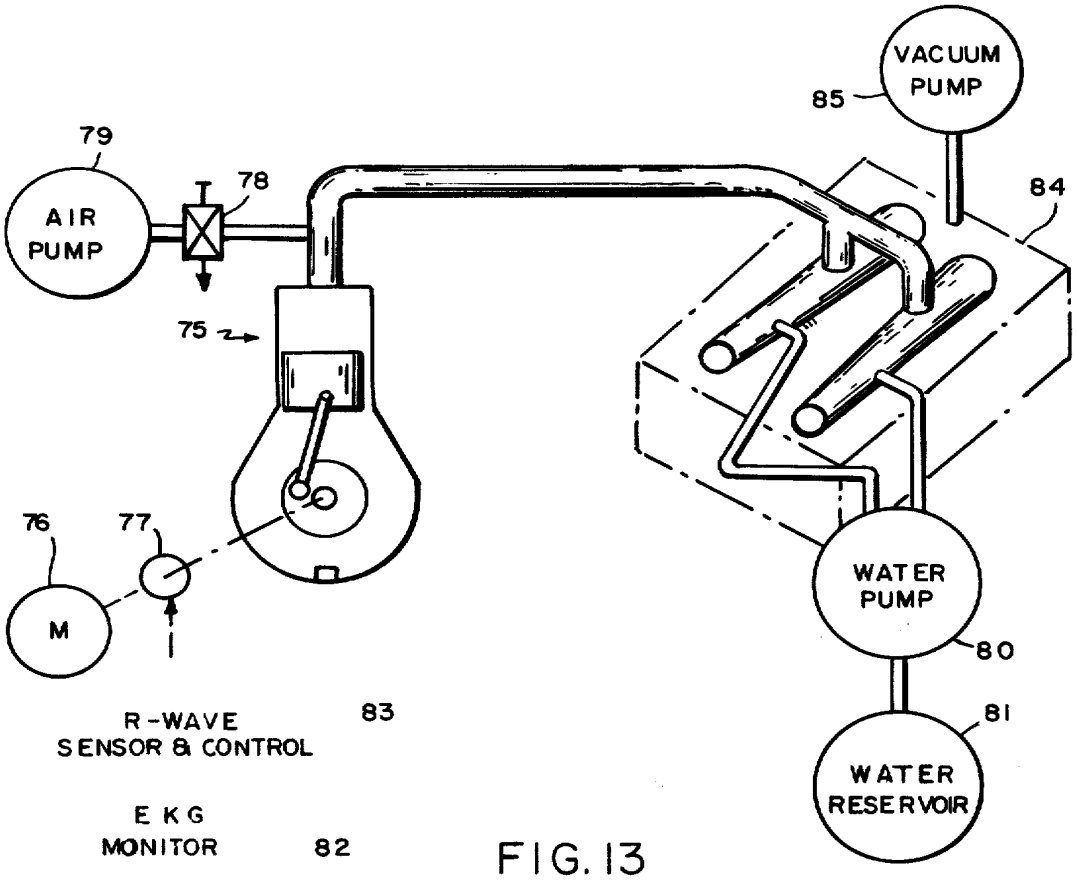

VACUUM
PUMP
85
79
78
84
AIR
PUMP
75
76
77
M
WATER
PUMP
80
81
WATER
RESERVOIR
R-WAVE
SENSOR & CONTROL
83
E K G
MONITOR
82

FIG. 13

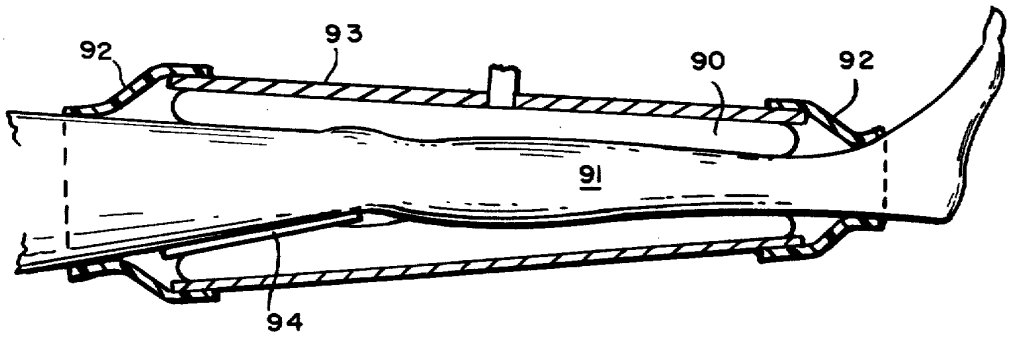


FIG. 14

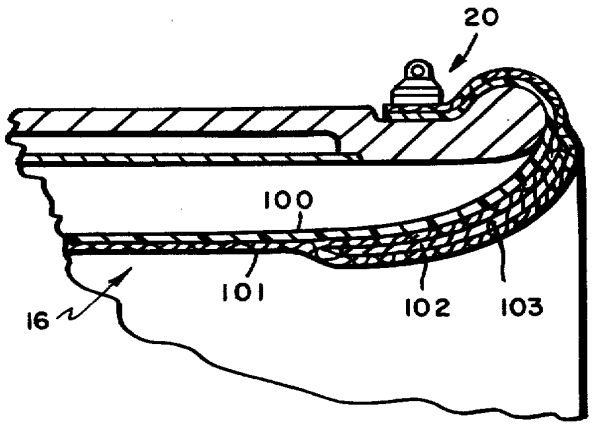


FIG. 15A

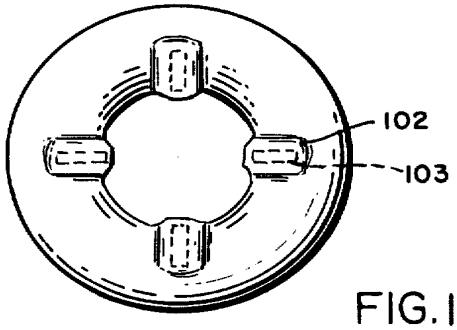


FIG. 15B

CARDIAC ASSIST APPARATUS

This invention relates generally to apparatus for assisting the circulation of blood in a human being and more particularly to an apparatus for doing so externally by the utilization of counter-pulsation techniques.

BACKGROUND OF THE INVENTION

Apparatus for providing external assistance in the circulation of blood in patients has been described in previously issued articles and patents, particularly U.S. Pat. No. 3,654,919 issued to W. C. Birtwell wherein a rigid housing encloses a portion of the patient's body, such as the legs, and a non-compressible hydraulic fluid is present within such housing. A suitable hydraulically actuated compression and decompression means is then utilized to cycle the pressure on said body portions via the non-compressible hydraulic fluid. Means are provided therein specifically to assure that the environment within the rigid housing is gas free so that no effective dead space is present and the efficiency of the compression and decompression energy transfer is maximized. Further, in the decompression portion of the cycle, a negative pressure is achieved immediately adjacent the body portion and means are provided for synchronously overriding the substmospheric pressure which is so obtained, such overriding being in appropriate synchronism with the patient's heartbeat.

A number of problems arise in the use of the device described in the above Birtwell patent. First of all, it is a relatively cumbersome structure to handle, the use of a non-compressible hydraulic fluid, such as water, making the overall apparatus quite heavy. Moreover, the hydraulic actuation equipment which is required to cause the compression and decompression flow of fluid within the housing must be placed relatively near the patient so as to avoid excessive hydraulic pressure drops along the fluid lines thereof, usually such actuator being placed on the table on which the patient himself lies, often substantially centrally located between the patient's legs, as shown in the patent.

Not only is such apparatus therein difficult to use because of the large size and weight of the rigid housings and the hydraulic fluid, together with the hydraulic actuation equipment therefor, but the presence of such elaborate equipment in the direct view of the patient may tend to produce an adverse psychological reaction on the part of the patient when the apparatus is being applied to the patient's limbs.

Moreover, the use of such rigid, fixed volume housing requires that they be made sufficiently large to fit the limbs of the largest patient to which the apparatus is expected to be applied. Thus, for patients with relatively small limbs, substantially more hydraulic liquid is required to fill the enclosure, a factor which only adds to the weight of the overall device and its difficulty in use.

In considering alternative structures for providing effective external assistance for the circulation of blood, the design thereof should provide for a reduction in the above disadvantages while still maintaining an effective energy transfer. The maintenance of such energy transfer must take into account the damping which may be present within the system, so that the effects thereof can be minimized and the overall efficiency of the system can be preserved.

Such damping can be broadly identified as arising from two major sources discussed in more detail below. A first source lies in the apparatus which comprises the system for producing the cyclic compression and decompression energy transfer to the patient's body. Such "system" damping can arise because of the distensibility of the housing which is used as well as the distensibility of the unsupported areas of the sealed portion of the system which contains the actuating fluid at the interface between the system and the portion of the patient's body to which the pulsating pressure is applied. Further, the instability of the shape of such sealed portion (i.e., the fact that such sealed portion does not retain its shape during the pulsating cycle) also contributes to the overall system damping. The compressibility of the actuating medium which gives rise to the presence of dead space within the housing also contributes to the system damping. Finally, both the presence of trapped air at various points within the system as well as the failure to provide an adequate contact between the sealed interface portion of the system and the patient's body can introduce additional damping into the system.

A second source of damping relates to the physical nature of the patient's body itself and can be best described as a form of "physiologic" damping. Such damping arises, for example, from the overall motion of the patient's body which can occur during the application of the pressure actuation system thereto. Additional factors which contribute to such physiologic damping include the displacement of body tissue, both in the areas to which the pressure is directly applied and in the areas adjacent thereto, and the compressibility of the body in those areas thereof which can contain gas, such as the abdomen and/or the thoracic cavity.

A primary consideration in the design of the structure disclosed in the above-mentioned Birtwell patent was the desire to reduce system damping which can arise because of the compressibility of the medium used to provide pressure actuation. Accordingly, such system used non-compressible hydraulic fluids, i.e., liquids, such as water, as the pressurizing medium in the sealed container at the interface with the patient's body, thereby necessitating the use of the hydraulic actuation and control system shown therein. While some consideration was given to the reduction of damping due to one or more of the other factors listed above (i.e., the utilization of a rigid, fixed volume housing, longitudinal tethering of the sealed container, etc.), little or no consideration was given to making the most effective use of the energy available, the hydraulic actuation system being arranged as an effectively open system where hydraulic fluid was continually supplied from the energy source. As a result, prime importance has been attached to the purported need to use non-compressible fluids, as opposed to compressible fluids, such as air, for pressure actuation and interface energy transfer so that damping at the interface of a rigid, fixed volume housing structure is minimized.

SUMMARY OF THE INVENTION

This invention, on the other hand, in one embodiment utilizes a compressible fluid, either alone or in combination with a non-compressible fluid, for energy transfer at the body interface. The use thereof provides an improved external assist apparatus which has the advantage of being lighter in weight and less cumbersome

to use than previously known apparatus, and further, which can be designed to reduce considerably the possibility of producing a traumatic experience for the patient. The effect of any increased interface damping which may result from the use of at least a partially compressible fluid medium is taken into account by utilizing a more efficient actuation system designed as a "closed" system wherein energy expended in transfer to the patient's body is effectively stored and returned to the system for reuse with a minimization of overall energy loss during operation. Such efficient use of energy overcomes the effects of increased damping due to the utilization of compressible fluids. Further, the effects of such increased damping can be overcome in other embodiments of the invention by utilizing housing units having adjustable volumes, the adjustment thereof being arranged to reduce the volume and, hence, the dead space which may give rise to damping at the interface of the medium with the patient's body.

More specifically, in one embodiment of the invention, for example, the housing is formed as a rigid, fixed volume type and the pressure is applied to the patient's body portion, such as the legs, through a medium which is at least partially in gaseous form. Because the pressure medium is, at least partly, a gas, such as air, the overall weight of the apparatus is reduced considerably and the compression and decompression cycle thereof can be actuated by the use of a pneumatic actuation system rather than a hydraulic system as in the prior art apparatus. Such a pneumatic actuator and control system can be placed at a position relatively remote from and out of the view of the patient without substantial pressure drops occurring in the pneumatic feed lines to the pressure applying medium. The use of a pneumatic actuation apparatus, which reduces the amount of equipment required to be located immediately adjacent the patient, thereby lessens the traumatic experience for the patient and provides more working space at the patient location for the medical personnel using the apparatus. Moreover, the reduction in weight makes the placement of the leg enclosure units on the patient much easier than with prior art devices. The pneumatic actuation system is designed so that some of the energy used to effect the desired pressure at the patient's limb is stored and reused so that the overall energy expenditure is at least comparable to that in the prior art structures which require hydraulic fluids for such purpose.

In still other embodiments of the apparatus of the invention utilizing such pneumatic actuation and control together with at least a partially gaseous pressure medium, the housing may be made of a rigid or semi-rigid material which is arranged to permit the formation of a variable volume of space within which the pressure medium is enclosed. Thus, the housing is designed to be so adjustable that a sufficiently small spatial volume can be achieved to reduce considerably the presence of dead space which may arise due to the compressibility of the gas. Moreover, the arrangement of a variable volume enclosure permits the configuration of such housings to be adjusted to patients of different sizes.

Particular embodiments of the invention are discussed in more detail below with the help of the accompanying drawings wherein

FIG. 1 shows a pictorial view of an overall system utilizing the apparatus of the invention;

FIG. 2 shows a view in longitudinal section of one embodiment of a body portion housing unit used in the apparatus of FIG. 1;

FIGS. 3 and 3A show both views in longitudinal and cross section of another embodiment of a body portion housing unit used in the apparatus of FIG. 1;

FIG. 4 shows a view in cross-section of the body portion housing unit of FIG. 2 taken along the lines 4—4 thereof;

FIG. 5 shows a view in cross-section of the body portion housing unit of FIG. 3 taken along the lines 5—5 thereof;

FIG. 6 shows a view in cross-section of a body portion housing unit utilizing one embodiment of a pressure medium comprising a gas-liquid combination;

FIG. 7 shows a view in cross-section of a body portion unit utilizing another embodiment of a gas-liquid pressure medium;

FIG. 8 shows a side elevational view of a body portion housing unit which has an adjustable configuration to permit the formation of a variable volume within;

FIG. 9 shows a view in cross-section of the body portion housing unit of FIG. 8 taken along the lines 9—9 thereof;

FIG. 10 shows another embodiment of a body portion housing unit utilizing a configuration of segmented cones;

FIG. 11 shows a view in cross-section of a portion of the housing unit shown in FIG. 10;

FIG. 12 shows a graph of one embodiment of the pressure waveform used in the system of the invention;

FIG. 13 shows a view, partially in block form and partially in diagrammatic form, of the pneumatic actuation system of the invention;

FIG. 14 shows a longitudinal section view of an alternate embodiment of the invention; and

FIGS. 15A and 15B show an alternative embodiment of the configuration shown in FIG. 2.

As shown in FIG. 1, the overall system in accordance with the invention comprises in one embodiment thereof a pair of leg units in the form of housings 10 which enclose a substantial portion of the legs of the patient to be treated. The leg units are generally formed to permit the lower leg from approximately the ankle region down to the foot to project outwardly from the lower end of the housing unit, the unit extending upwardly therefrom to the upper leg in the region of the thighs. Separate leg units may be used, or such units may be joined at their upper ends either by fixed connections to form a fixed angle with respect to each other or by pivotal connections so that such angle may be suitably varied as desired.

As described in more detail below, the leg units enclose a pressurizeable medium which acts as an interface between the surface of the legs of the patient within the housing and a pressure actuation and control system 11. The medium as discussed below can be either fully gaseous or at least partially gaseous and is actuated by a pneumatic pressure actuation system which cyclically feeds gas under pressure via tubings 12 to each of the leg units and then removes said gas by reversal of said pressure to sub-atmospheric levels in a cyclic fashion. Alternatively, the gas may be fed by a single tubing from the actuator and then supplied to each housing by a pair of branch tubings connected thereto by a suitable T-connection arrangement.

Accordingly, an appropriate compression and decompression of the patient's legs will occur so as to assist the circulation of the blood, the cyclical application thereof being in appropriate synchronism with the patient's heartbeat as described in the aforementioned Birtwell patent, and as described, for example, in the article "Support of the Systemic Circulation and Left Ventricular Assist by Synchronous Pulsation of Extramural Pressure," Birtwell et al., Vol. XI, Trans. Amer. Soc. Artif. Int. Organs, 1965.

One embodiment of leg units **10** is described in more detail in FIGS. **2** and **4** wherein it can be seen that each leg unit comprises a rigid housing **15** in a substantially frusto-conical shape, such housing in the embodiment described being made of aluminum or an appropriate rigid plastic material as desired. A flexible, fluid-tight material forms a sealed member **16** which is pressure expansible the material thereof being preferably non-distensible. The material is formed in a tubular shape and mounted within the rigid enclosure so as to completely enclose the major portion of the leg **17** of the patient (not shown), the surface of the plastic material generally conforming to the contour of the patient's leg. In the embodiment shown the flexible material is attached to the rigid housing by lapping the ends thereof over the rounded ends **18** of the housing so as to permit the overlapped ends to rest in notches **19** of the housing over which notches appropriate sealing rings **20** may be attached. As used herein the term "flexible material" may include thermosetting and thermoplastic elastomeric materials and may also include, for example, multi-layered materials, such as one having a first inner layer of distensible material and a second outer layer of a non-distensible material, such as one having a layer of rubber backed by a layer of cloth.

A fitting **21** is integrally formed in housing **15** to provide an opening **22** at the exterior surface of the housing which can be suitably connected to the pneumatic pressure actuation system **11** which supplies gas under pressure at above atmospheric pressure throughout a first portion of its cycle and which removes gas to create a subatmospheric pressure within the sealed member **16** during the remaining portion of its cycle.

The pressurizeable medium is introduced into the spatial volume between flexible sealed member **16** and the inner wall **23** of housing **15** so that as the pressure therein increases during the compression portion of the cycle the pressure medium presses against the patient's leg as desired. A perforated tubular member **24** is attached by suitable means such as an adhesive to shoulders **15A** at the interior of housing **15** in the space between member **16** and housing **15** at about a position midway therebetween. Member **24** may be a rigid plastic material, for example, and prevents the flexible member from collapsing completely against and adhering to the interior wall of housing **15** during the decompression portion of the cycle, which collapse may cause an effective but undesirable valving action which would prevent an efficient transfer of oscillatory energy from the actuator to the leg. Member **16** can be made of any suitable thin metallic or plastic material, such as aluminum or acetal, for example.

In the embodiment shown in FIGS. **3**, **3A** and **5**, the member which contains the pressurizeable medium is formed separately from the rigid housing itself. As can be seen therein a flexible, tubular sealed container **25** is made of a suitable flexible material such as nylon-neoprene cloth, for example. In a collapsed state the container may be folded flat or rolled up into a compact annular shape. When the apparatus is to be used, the container **25** is suitably unfurled and placed, as shown in FIG. **3**, within the housing over the patient's leg. The container has an appropriate integrally-formed fitting **26** which is inserted through a suitable opening in a rigid housing **27** and which is adapted to be connected to a pressure actuation source. The flexible container **25** is thereby enclosed by the rigid housing **27** which as seen in FIG. **5** can be constructed for this purpose in two pieces, **27A** and **27B**, which are hingedly connected. During use, the major portion of the patient's leg is encased in flexible container **25**, is placed in lower piece **27B** and the upper piece **27A** is rotated to a closed position and clamped to the lower piece by any suitable conventional clamping mechanism **28** to form a rigid housing around container **25**.

In order to prevent any valving action in the embodiment of FIG. **3** appropriate manifolding means may be used within the interior thereof to prevent collapse of the outer surface thereof against the inner surface adjacent the wall of the housing. One suitable manifolding means as shown in FIG. **3** can comprise an interior layer of rubber material **29** adjacent the housing wall, such layer having a plurality of projections **29A** extending toward the interior of container **25** as shown.

In the embodiments discussed above with reference to FIGS. **1–5**, as well as in the embodiments of the prior art, a longitudinal force difference tends to exist along the patient's legs during operation of the system because of the difference in the cross-sectional area at the patient's thighs and that at the patient's ankles. Such force differential causes the inner wall of the sealed members of the apparatus (i.e., the direct interface of the inner wall of flexible members **16** or **25** in contact with the patient's leg in FIGS. **2** and **3**, for example) to move longitudinally with respect to the outer wall thereof (i.e., the housing wall in FIG. **2** or the outer wall of flexible container **25** in FIG. **3** which is in contact with the housing). As a result, such movement tends to move the legs and, hence, the entire body of the patient outwardly from the housing and, in effect, to forcibly eject the patient from the housing units, thereby reducing the effectiveness of the system to perform its task as well as producing discomfort and a further traumatic effect on the patient.

In order to overcome such movement it is desirable to longitudinally tether at least a portion of the inner wall of the sealed member to the housing (FIG. **2**) or to the outer wall thereof adjacent the housing (FIG. **3**). It has been found that if such tethering is effected, for example, along two or four parallel lines near each end of the housing, longitudinal movement of the inner wall of container **25** is reduced considerably. Four such tether lines **25A** are shown in an exemplary embodiment of FIGS. **3** and **3A**. Although the tethered portions may extend the entire length of the housing, it is not found necessary to do so in all applications, and tethering at the ends thereof may be sufficient. Accordingly, they may be arranged in preferred embodiments, for example, to extend inwardly from each end thereof to lengths of about 10–20 percent of the total housing length. Moreover, additional tethered portions may be used at other positions in addition to the ends thereof, if desired.

In the embodiment of FIGS. **2** and **24** the tethered portions **16A** of the inner wall of container **16** may be arranged to be suitably tethered to the rounded end **18** of the housing and to the ends of perforated member **24** as shown therein. Alternatively, in FIG. **2** the ends of the sealed member **16** may be effectively tethered without the necessity for adhering member **16** to the housing wall. For example, FIGS. **15A** and **15B** show an alternative structure wherein the flexible member is formed of a multi-layer material in which a first inner layer **100** is rubber and a second outer layer **101** is cloth. A plurality of generally longitudinally directed pockets **102** are formed between the layers at each end thereof (for simplicity only a view of one end is shown in FIG. **15B** and only a part thereof in FIG. **15A**). The extreme end of member **16** is held by the sealing ring **20** in the manner discussed above with reference to FIG. **2** and the pockets **102** extend from a point within the interior of the housing to a point approximately adjacent the region where member **16** overlaps the rounded end **18** of the housing. A plurality of spring-like, or semi-rigid, stays **103** are inserted in the plurality of pockets at each end of flexible member **16** so as to project inwardly of the housing. The use of such stays tends to prevent longitudinal motion of the ends of flexible member **16** relative to the housing **16** so that such ends are effectively tethered thereby.

The pressurization medium in the above embodiments can be either fully gaseous or may be a gas-liquid combination depending upon the application which is desired. In permanent installations, for example, where sufficient power is available for the use of relatively large motors (e.g., over 1 horsepower), the medium can be completely gaseous and dead space problems can be overcome by installing a suitably sized motor to operate under all expected dead-space conditions. Even in portable, or less permanently installed, apparatus a completely gaseous medium can often be used relatively effectively with smaller motors of less than 1 horsepower because of the effective utilization of energy brought about by the use of a closed pneumatic actuation system as discussed further below.

A further advantage of the use of pneumatic systems in this regard is that the compressible gaseous medium can inherently achieve the desired negative pressures with less expenditure of energy from the energy input source than is required when using an hydraulic medium, such as water. Thus, the use of a gaseous medium eliminates the static head which is present when using an hydraulic medium which completely surrounds the patient's limb. In the latter case the positive head must be overcome before any negative pressure is obtained. Such an advantage in using a pneumatic system then tends further to offset any disadvantage which may arise because of any increase in damping due to the use of a compressible gaseous medium. This advantage can still be obtained even when using a combined gas/liquid medium, particularly with the system discussed below with reference to FIG. **6** where the liquid portion thereof is maintained substantially below the patient's leg so that no static head is present.

If the dead space which exists due to the compressibility of the gaseous medium tends to prevent the creation of sufficient pressures as required and if sufficiently large actuator systems are not available to overcome such problem, such dead space may be reduced by using an apparatus which utilizes a combined gas-liquid pressure medium as shown with reference to FIGS. **6** and **7**. As can be seen in FIG. **6**, for example, a housing **30** of the form shown in FIG. **4**, for example, has a sealed flexible container **31** which substantially conforms to the patient's leg and has contained therein a liquid medium **32** and a gaseous medium **33** in direct contact therewith. In a practical embodiment, for example, the liquid medium such as water, may preferably be approximately 50 percent, or more, of the volume within the housing. A pneumatic actuation system as shown in FIG. **1** is then appropriately connected to fitting **34** so that the gaseous medium, such as air, can be pressurized, the liquid medium taking up substantially most of the dead space that may occur within the sealed enclosure due to the compressibility of the gaseous medium. In this way, a relatively efficient transfer of pressure to the leg can be achieved.

Another embodiment of a combined gas-liquid pressurizeable medium is shown in FIG. **7**. As can be seen therein, the liquid medium **42** and the gas medium **43** are separated from each other, the liquid medium being placed in a flexible sealed container **41** which encircles the leg of the patient and forms the direct pressure interface with the patient's body. The gas coupling medium **43** is inserted into the housing **40** between the sealed liquid container **41** and the interior surface of housing **40**. An appropriate fitting **44** is connected to a pneumatic actuation system for inserting and withdrawing gas above and below atmospheric pressure, which gas pressure variations are coupled via gas medium **43** to the liquid medium **42** and then to the patient's leg for providing the cyclic compression and decompression action required.

While the use of rigid, fixed volume housing units as shown in FIGS. **2–7** are useful in many applications, it is desirable in still other applications to provide for rigid or semi-rigid housings having adjustable volumes particularly for permitting an adjustment thereof when used with patients having different limb sizes, which adjustment can also be used to reduce any dead space which may exist when such structure is used with a completely or partially compressible medium. One embodiment of such a variable volume housing is shown in FIGS. **8** and **9**, the diameter of which can be varied at varous points along the length thereof. For example, the housing **50** may be made in the form of a collapsible, or adjustable, sheet of metallic material, such as sheet aluminum, which is formed in an overlapping manner into a substantially frusto-conical shape. A plurality of adjustable bands, or rings **51** are placed at selected positions along the length thereof. The patient's leg is inserted into the housing when the bands are in a relatively loose condition so that an effectively large diameter housing is formed. The bands are then tightened so as to reduce the volume of the space between the housing and the patient's limb in which a sealed container **52** fits. Thus, the dead space, which ordinarily may be present when a compressible medium, such as air, is completely or partially used as the pressurizeable medium can be minimized no matter what the size of the patient's leg. Accordingly, the efficiency of the overall pneumatic actuation system can be increased thereby enhancing the capability of the system to operate even with pressure actuation systems of relatively low power.

The variable volume structure shown can also use a completely non-compressible medium. In such a case,

because the variable volume housing structure permits a closer conformity of the housing to the legs of the patient, less hydraulic fluid is required than in those fixed volume structures of the prior art so that a consequent overall reduction in weight of the portion of the apparatus at the patient's legs occurs. Further, the volume adjustments permit a closer conformity of the overall sealed container to the patient's body and tends to reduce the unsupported annular end regions of the flexible container and, accordingly, the damping due thereto. Further, as the housing volume is reduced, a better conformability of the tethered portions of the sealed container to the patient's body results.

Another embodiment of a rigid, or semi-rigid housing which can be utilized to make the most efficient use of the apparatus of the invention for different size patients is shown in FIG. **10.** As can be seen therein, a relatively large frusto-conically shaped housing **60** can be formed from a plurality of segmented frusto-conical members **61** each of which can be suitably attached and detached to adjacent of said members having corresponding diameters. In the process of use, a selectable portion of the overall housing can be formed in accordance with the size of the patient's leg. For example, in the illustrated embodiment of a segmented housing of FIG. **10,** seven separable segments A–G are depicted, segments A, B, C, E, F, G being of approximately the same length and segment D being approximately three times larger in the specific embodiment shown. The overall housing with all segments attached together is made available for use with a patient. For use with a patient having a relatively small diameter leg, sections A, B, C, D and E may be selected and the segmented sections F and G may be detached therefrom. For a medium sized leg, it may be desirable to utilize only sections B, C, D, E and F with sections A and G detached therefrom. For relatively large legs it may be desirable to use sections C, D, E, F and G with sections A and B detached therefrom. Accordingly, the amount of dead space which is present for use in a system using a complete or partial gaseous medium can be minimized by the appropriate selection of segments in accordance with the size of a patient's leg. The segments shown in FIG. **10** can be attached by appropriate means as shown in the exemplary embodiment of FIG. **11.** As seen therein if housing segments, each of the type shown in FIG. **2,** are used the flexible containers **62A** or **62B** of adjacent segments are lapped over the corresponding ends **63A** and **63B** thereof to rest in notches **64A** and **64B.** Clamp members **65A** and **65B** have first flanges **66A** and **66B** which rest in notches **64A** and **64B** respectively, above the lapped ends of the flexible containers therein. Upright flanges **67A** and **67B** lie adjacent each other at the junction of the housing segments and are appropriately clamped to each other at suitable points located on the periphery of the housings via threaded bolts **68** inserted through threaded openings in the upright flanges. The flanges **66A** and **66B** are retained in the notched ends of the housing segments by suitable clamping bands **69A** and **69B,** respectively, as shown.

In a preferred embodiment of the invention the pneumatic actuation system which is utilized will provide an effective sinusoidal pressure wave form **70** as shown in FIG. **12.** As can be seen therein, the pressure can vary in a particular embodiment from a minimum valve within a preferred range of approximately +25 mm. Hg. to −50 mm. Hg., although such minimum value may be set otherwise in some applications, to a maximum value within a preferred range of approximately 200 mm. Hg. to 250 mm. Hg., although such maximum value also may be set otherwise in some applications. The rise time is defined as the time the pressure rises from a low value equal to 10 percent of the peak-to-peak value thereof to a value equal to 90 percent of such peak-to-peak value, with the fall time being similarly defined as the time the pressure decreases from 90 percent of its peak-to-peak value to 10 percent thereof. A preferred rise time and a preferred fall time is usually set within a range of 80–150 milliseconds in each case.

The time duration of the pulsating portion of the wave form is defined as the time for the pressure wave form to rise from a low value at 10 percent of its peak-to-peak value to a time when it has passed through its positive peak value to a value of 90 percent of the peak-to-peak value thereof. Such time may preferably lie within a range of about 200–500 milliseconds.

Although a sine wave is shown in FIG. **12,** the system is not limited to such a wave form. A square wave configuration may be acceptable in some applications if the discrete changes thereof do not cause adverse effects on the patient. Other wave shapes may be devised also for such purpose.

A pneumatic actuation system for achieving an appropriate pressure wave form is shown in FIG. **13** wherein it can be seen that a suitably sized crank driven piston **75,** fitted with conventional low friction, low hysteresis seals and driven by a variable speed gear motor **76** through an appropriate clutch/brake combination **77,** provides a means for producing synchronous pneumatic pressure pulses of the wave shape described above, such pressure pulses being applied to the coupling medium at the interface with the patient's limb to create the desired hemodynamic results. Appropriate and known means can be utilized to adjust the amplitude of the pressure pulse and the relationship of the positive and negative peak pressure amplitudes with ambient (room atmospheric) pressure.

Thus, if the atmospheric pressure volume of the medium in the pneumatic actuation system is such that the piston stroke is at its mid-stroke position, driving the piston in one direction (forward) will create a positive pressure and driving it in the opposite direction (backward) will create a negative pressure. Any appropriate combination of positive and negative peak pressures can be arranged within the total pressure differential capability of the pump system and can be selected for an individual patient by adjustment of the total volume of fluid in the system (often referred to as the "charge" on the system) to produce the optimum hemodynamic results which are desired. Such volume adjustment can be made by adjustment of valve **78** which supplies air from air pump **79** to the system. In a system which uses an air/liquid combination or in a variable volume system which uses a liquid medium alone, the hydraulic liquid can be supplied from a liquid reservoir **81** via a suitable pump **80.** Appropriate synchronism with the patient's heartbeat can then be provided by suitable monitoring of the patient's EKG by monitor **82,** a sensing of the R wave of the patient's heartbeat to provide suitable control of the operation of the clutch/brake combination **77** and, accordingly, of the piston motion of the actuation system relative to the R wave, as shown by the R-wave sensor and control device **83.** Such syn-

chronization and control is explained in more detail, for example, in the article cited above.

The effectiveness in achieving a negative pressure at the patient's body is dependent upon how good a seal is maintained between the inner surface of the sealed container containing the energy coupling medium and the surface of the patient's limbs during the negative portion of the pulsation cycle. Such seal can be maintained by the use of an adhesive compound on the surface of the sealed container between the container and the limb. However, such a method may be impractical or inappropriate in many situations.

Another method for providing such a seal is to evacuate all of the air between the limb and the sealed container outer surface, such evacuation being maintained against the levels of those peak negative pressures being created by the pneumatic actuation system applied through the actuation fluid in the sealed container. Thus, a continuous suction can be created in the space between the limb and the sealed container by an external evacuation device. One method of achieving this is to enclose the legs and housing units of the system by a vacuum enclosure **84** as shown by the dashed line in FIG. **13**, such enclosure being appropriately evacuated by an external vacuum pump **85** which creates a zone of sub-atmospheric pressure below that expected at the lowest region of the pressure actuation curve of FIG. **12** around such housing system.

A further method of providing an appropriate seal is to arrange for an effective self-evacuation system for such purpose, thereby eliminating the need for a vacuum enclosure and external vacuum pump. Since the sub-atmospheric pressure in the space between the sealed container and the patient's body is required only during the time when the pressure wave form is below atmospheric pressure, such time being a relatively short part of the overall pressure cycle, there need not be a requirement for a constant negative pressure as would exist in the above described externally actuated evacuation system. Such a self-evacuation system is shown in FIG. **14**. As seen therein, the ends of the space between the sealed container **90** and the patient's legs **91** at the ankles and at the thighs are fitted with passive one-way valves **92** which permit the expulsion of air from such space to the atmosphere but which prevent the intake of air from the atmosphere to such space. Such valves may be in the form of thin rubber rings placed over the ends of the housing **93**, the free ends thereof being held tightly against the patient's ankles and thighs when applied. During each positive pressure portion of the pressure wave form, the ends of the one-way valves are opened and substantially all of the air in the space between the leg and the sealed container is expelled therefrom. During the negative portions of the pressure wave form the ends thereof are closed and an effective evacuation of the space between the limb and container is maintained. While the air is vented to the atmosphere in the embodiment shown in FIG. **14** the output valves may alternatively be attached to suitable suction pumps to further insure that no air will leak back into such space during the negative pressure phase of the pressure wave form. In order to prevent valving of the container a suitable manifold means **94** may be placed within the container. Such manifold means may be in the form of a rigid tubular structure preferably extending from the region below the knee to the end of the housing. The manifold provides a passageway for any trapped air that may be present, such trapped air being most likely to be present at such knee region. In those embodiments which utilize tethers, as discussed above, the presence of the tethers may be sufficient to provide such passageways without the need for such an additional manifold means.

The above description shows various embodiments of the invention, although other embodiments within the scope of the invention may occur to those in the art. Hence, the invention is not to be construed as limited to the particular embodiments shown herein except as defined by the appended claims.

The following U.S. Pat. Nos. were obtained by a patent search: **1,608,239, 2,113,253, 2,168,611,** 2,345,073, 2,361,242, 3,179,106, 3,268,711, 3,288,132, 3,292,613, 3,303,841, 3,307,533, 3,329,142, 3,403,673, 3,411,496, 3,548,809, 3,599,631, 3,651,801, 3,654,919, 3,659,593, 3,674,018, 3,693,627.

What is claimed is:

1. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion which is in gaseous form, enclosed in a flexible sealed member which is pressure expansible and positioned between said pressure actuation means and said portion of the patient's body, at least a part of said sealed member being in contact with said body portion, a first portion of said sealed member being formed of a flexible material sealably clamped to the ends of said housing and a second portion thereof being formed by said housing, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat; and

means for preventing said flexible material from collapsing against said housing during the decompression portion of the cyclical application of said pressure.

2. An apparatus in accordance with claim **1** wherein at least selected portions of said flexible material are tethered to portions of said housing to prevent the tendency for relative movement between said flexible material and said housing.

3. An apparatus in accordance with claim **2** wherein said flexible material is tethered to said housing substantially at the ends thereof.

4. An apparatus in accordance with claim **1** wherein said last-named means is a perforated tubular member positioned within said housing between said housing and said flexible material.

5. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, enclosed in a flexible sealed member which is pressure expansible and positioned between said pressure actuation means and said portion of the patient's body, said sealed member being a flexible tubular means formed independently of said housing, said sealed member being positioned during operation of said apparatus between the inner wall of said housing and said body portion to flexibly enclose said body portion, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

means for preventing the walls of said flexible sealed member from collapsing against each other during the decompression portion of the cyclical application of said pressure; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

6. An apparatus in accordance with claim **5** wherein portions of the inner wall of said flexible sealed member adjacent said body portion are tethered to portions of the outer wall thereof adjacent said housing to prevent the tendency for relative movement of said inner and outer walls.

7. An apparatus in accordance with claim **6** wherein said tethered portions are substantially at the ends of said flexible sealed member.

8. An apparatus in accordance with claim **5** wherein said said preventing means means comprises a flexible means having a plurality of projections extending into the interior of said sealed member.

9. apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body, said housing comprising

a pair of hingedly connected portions pivotally movable relative to each other from an open to a closed position;

means for clamping said portions together in said closed position;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, enclosed in a flexible sealed member which is pressure expansible, at least a part of said sealed member being in contact with said body portion, and positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

10. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium enclosed in a flexible sealed member which is pressure expansible and positioned between said pressure actuation means and said portion of the patient's body, at least a part of said sealed member being in contact with said body portion, said pressure medium being a combination of a gaseous material and a liquid material placed within said flexible sealed member in contact with each other and further being responsive to said pneumatic pressure actuation means to apply pressure to said body portion; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

11. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

said pressure medium being a combination of a gaseous material and a liquid material;

said liquid material being placed within a first flexible sealed member in contact with said body portion;

said gaseous material being placed within the said housing between said first flexible sealed member and said housing;

said pneumatic pressure actuation means being coupled to said gaseous material; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

12. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means having a substantially fixed volume for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

said pressure medium being a combination of a gaseous material and a liquid material;

said gaseous material being placed within a flexible sealed member in contact with and enclosing said body portion;

said liquid material being placed within said housing between said flexible gaseous container and said housing;

said pneumatic actuation means being coupled to said liquid material; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

13. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means for enclosing a portion of said patient's body, said housing means including means for adjusting the volume enclosed thereby to provide for a variable volume when enclosing said body portion;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion; and means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

14. Apparatus in accordance with claim **13** wherein said pressure medium is enclosed in a flexible sealed member which is pressure expansible, at least a part of said sealed member being in contact with said body portion.

15. Apparatus in accordance with claim **14** wherein a first portion of said sealed member is formed of a flexible material sealably clamped to the ends of said housing and a second portion thereof is formed by said housing.

16. Apparatus in accordance with claim **14** wherein said sealed member is a flexible tubular means formed independently of said housing, said sealed member being positioned during operation of said apparatus between the inner wall of said housing and said body portion to flexibly enclose said body portion.

17. Apparatus in accordance with claim **13** wherein said pressure medium is a combination of a gaseous material and a liquid material placed within a flexible sealed member in contact with each other.

18. Apparatus in accordance with claim **13** wherein said pressure medium is a combination of a gaseous material and a liquid material;

said liquid material being placed within a first flexible sealed member in contact with said body portion;

said gaseous material is placed within the said housing between said flexible sealed member and said housing; and

said pneumatic pressure actuation means is coupled to said gaseous material.

19. Apparatus in accordance with claim **13** wherein said pressure medium is a combination of a gaseous material and a liquid material;

said gaseous material being contained within a flexible sealed member in contact with and enclosing said body portion;

said liquid material being placed within said housing between said flexible sealed member and said housing; and

said pneumatic actuation means is coupled to said liquid material.

20. An apparatus in accordance with claim **13** wherein

said housing is formed of sheet metal being arranged in a substantially frusto-conical shape and having overlapping portions along the longitudinal direction thereof; and

said adjusting means providing for the adjustment of the amount of overlap of said overlapping portions to permit adjustment of the volume enclosed thereby.

21. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means for enclosing a portion of said patient's body;

means for adjusting the volume enclosed by said housing means to provide for a variable volume when enclosing said body portion;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

pressure actuation means;

a liquid pressure medium enclosed in a flexible sealed member which is pressure expansible, said sealed member being positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pressure actuation means to apply pressure to said body portion; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

22. Apparatus in accordance with claim **21** wherein said pressure actuation means is a hydraulic pressure actuation means coupled to said liquid material in said flexible sealed member.

23. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means for enclosing a portion of said patient's body;

said housing means comprising a plurality of frusto-conical segments and further including

means for affixing a selected number of said segments to one another to form a substantially rigid housing of a selected length and having openings at the ends thereof of predetermined diameters for use with body portions of different sizes;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion; and

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat.

24. Apparatus for providing external assistance for the circulation of blood in a patient comprising

substantially rigid housing means for enclosing a portion of said patient's body;

means for cyclically applying pressure to said body portion within said housing means, said pressure applying means including

a closed pneumatic pressure actuation means;

a pressure medium, at least a portion of which is in gaseous form, positioned between said pressure actuation means and said portion of the patient's body, said pressure medium being responsive to said pneumatic pressure actuation means to apply pressure to said body portion;

means for synchronizing the operation of said pressure actuation means to apply said pressure cyclically to produce alternating compression and decompression of said body portion in synchronism with said patient's heartbeat;

an evacuation chamber enclosing said housing means and the body portion enclosed by said housing; and

vacuum pump means for maintaining a pressure within said evacuation chamber at a level below the lowest pressure achieved during the decompression portion of the cyclical pressure applied to said body portion.

25. An apparatus in accordance with claim **23** wherein said one-way valve comprises a flexible ring positioned over the ends of said housing, the free ends of said ring being held tightly against the body portions of said patient at said ends.

26. An apparatus in accordance with claim **25** and further including manifold means for conveying trapped air from the interior of said housing to said end regions thereof.

27. An apparatus in accordance with claim **24** wherein the ends of said member include

a plurality of pockets formed therein between said layers; and

a substantially rigid stay positioned in each of said pockets;

whereby the tendency for said flexible sealed member to move relative to said housing tends to be reduced.

28. An apparatus in accordance with claim **9** and further including one-way valve means positioned at the common ends of said housing and said flexible sealed member to permit the expulsion of air from the region at said ends during the compression portion of said cyclically applied pressure and to prevent the intake of air into said region during the decompression portion of said cyclically applied pressure, thereby to maintain an effective evacuation of air in said region during said decompression portion.

29. An apparatus in accordance with claim **1** wherein said flexible sealed member is formed of a first layer of rubberlike material and a second layer of cloth-like material.

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